CONFIDENTIAL

SINGAPORE ACCREDITATION COUNCIL
SINGAPORE LABORATORY ACCREDITATION SCHEME (SAC-SINGLAS)

MEDICAL TESTING LABORATORY / MEDICAL IMAGING FACILITY ASSESSMENT CHECKLIST [ISO 15189: 2022]

Type of Assessment	:	Preliminary / Initial / Renewal / Surveillance / Non-Routine / Verification
Name of Laboratory / Facility	:	
Address	:	
Tel	:	
Names of persons seen	:	
Field & Disciplines	:	
Date(s) of visit	:	
Technical Assessor(s)	:	
Team Leader	:	Name / Date

References
ISO 15189:2022, SAC-01, SAC-02, SAC-SINGLAS 001, SAC-SINGLAS-006, PROF 001, MED 001 and MED 002, MI 001

	Description
To Produce	Mandatory to meet the requirement
To Consider	Guidance to meet the requirement

Clause No	Description	Yes	No	N/A	Remarks
4	**GENERAL REQUIREMENTS**				
4.1	**Impartiality** Does the laboratory demonstrate its management commitment to impartiality of its laboratory activities? To consider • Organisation chart • Code of conduct / impartiality policy • Declaration of impartiality (commercial, financial, or other pressures) • Monitor and identified threats to its impartiality Does the laboratory eliminate or minimise the effect when a threat to impartiality is identified?				
4.2	**Confidentiality**				
4.2.1	**Management of information** How is the laboratory responsible for the management of all patient information obtained or created during the performance of laboratory activities? To consider • Agreements of privacy and confidentiality of patient information. • Policy and procedures to ensure confidentiality Does the laboratory inform the user and/or patient in advance if it intends to place the information in the public domain?				
4.2.2	**Release of information** Is the patient notified when it is required by law or authorised by contractual agreements to release confidential information? (unless prohibited by law) Does the laboratory maintain confidentiality of the following: • Information about the patient, which is obtained from a third party (e.g. complainant / regulators)? • Identity of the source and not share with the patient, unless agreed by the source?				

Clause No	Description	Yes	No	N/A	Remarks
4.2.3	**Personnel responsibility** Does the laboratory ensure that all personnel maintain confidentiality of all information obtained during the laboratory activities?				
4.3	**<u>Requirements regarding patients</u>** Does the laboratory management ensure that patients' well-being, safety and rights are of primary consideration through implementation of the following processes?				
a)	Offer opportunities for patients and laboratory users to provide helpful information to aid the laboratory in the selection of the examination methods, and the interpretation of the examination results				
b)	Provide patients and users with publicly available information about the examination process, including costs when applicable, and expected turn-around-time				
c)	Periodic review of the examinations offered by the laboratory to ensure they are clinically appropriate and necessary				
d)	Disclose to patients, users and any other relevant persons, of incidents that resulted or could have results in patient harm, and records of actions taken to mitigate those harms, where appropriate				
e)	Treat patients, their samples or remains, with due care and respect				
f)	Obtain informed consent when required				
g)	Ensure the ongoing availability and integrity of retained patient samples and records in the event of the closure, acquisition or merger of the laboratory				
h)	Make relevant information available to a patient and any other health service provider at the request of the patient or the request of a healthcare provider acting on their behalf				
i)	Uphold the rights of patients to care that is free from discrimination				

Clause No	Description	Yes	No	N/A	Remarks
5	**STRUCTURAL AND GOVERNANCE REQUIREMENTS**				
5.1	**Legal entity** Is the laboratory or the organisation legally responsible for its activities? To produce • Valid ACRA Certificate • Company registration number • HCSA License				
5.2	**Laboratory director**				
5.2.1	Does the person have the specified qualifications, competence, delegated authority, responsibility and resources to fulfil the requirements of this standard?				
5.2.2	Is the laboratory director responsible for the implementation of the management system, including risk management? Are the duties and responsibilities of the laboratory director documented?				
5.2.3	Does the laboratory document the delegation of the laboratory director's responsibility?				
5.3	**Laboratory activities**				
5.3.1	Does the laboratory specify and document the range of laboratory activities, including activities performed at sites other than the main location (e.g. POCT, sample collection)? • Laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.				
5.3.2	**Conformance with requirements** Are laboratory activities carried out in a way as to meet the requirements of this document, users, regulatory authorities and organisations providing recognition? • This applies to the complete range of specified and documented laboratory activities, regardless of where the service is provided.				

Clause No	Description	Yes	No	N/A	Remarks
5.3.3	**Advisory activities** Does the laboratory establish arrangements for communication with laboratory users on appropriate laboratory advice and interpretation are available and meet the needs of patients and users? • Choice and use of examinations • Professional judgements • Effective utilisation of laboratory examinations • Scientific and logistical matters				
5.4	**Structure and authority**				
5.4.1	Does the laboratory:				
a)	Define the organisation and management structure, its place in any parent organisation and the relationships between management, technical operations and support services				
b)	Specify the responsibility, authority, lines of communication and interrelationship of all personnel who manage, perform or verify work affecting the results				
c)	Document necessary procedures to ensure consistent application of its activities and the validity of its results To consider Job description, Organisation chart, Roles and Responsibilities, Standard Operating Procedures				
5.4.2	Does the laboratory have authorised personnel to:				
a)	Implement, maintain and improve the management system				
b) and c)	Identify deviations and initiate actions to minimize or prevent such deviations				
d)	Report to management on the performance of the management system and any need for improvements				
e)	Ensure the effectiveness of laboratory activities				
5.5	**Objectives and policies**				
a), b) and c)	Does the laboratory management establish and maintain measured and consistent objectives and policies to • Meet the needs and requirements of patients and users • Commit to good professional practice • Provide examinations that fulfil their intended use				

Clause No	Description	Yes	No	N/A	Remarks
	• Implemented at all levels of the laboratory organisation • Ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented				
d)	Does the laboratory establish quality indicators to evaluate performance throughout key aspects of pre-examination, examination and post-examination processes and monitor the performance in relation to the objectives?				
5.6	**Risk management**				
a)	Does the laboratory management establish, implement and maintain processes for identifying risks of harm to patients and opportunities for improved patient care and develop actions to address both risk and opportunities for improvement?				
b)	Does the laboratory director ensure that these processes are evaluated for effectiveness and modified when identified as ineffective?				
6	**RESOURCE REQUIREMENTS**				
6.1	Does the laboratory have available personnel, facilities, equipment, reagents, consumables and support services necessary to manage and perform its activities?				
6.2	**Personnel**				
6.2.1	**General**				
a)	Does the laboratory have access to a sufficient number of competent persons to perform its activities?				
b)	Are all personnel, internal and external, that could influence the laboratory activities act impartially, ethically, be competent and work in accordance with the laboratory's management system?				
c)	Does the laboratory communicate to personnel the importance of meeting the needs and requirements of users and this document?				
d)	Does the laboratory have a programme to introduce personnel to the organisation, department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements and occupational health services?				

Clause No	Description	Yes	No	N/A	Remarks
6.2.2	**Competence requirements**				
a)	Does the laboratory document the competence requirements for each function that may influence the results of laboratory activities? • Education • Qualification • Training and Re-training • Technical knowledge, skills and experience <u>To consider</u> • Training and Competency Matrix • Job description • Training records • Curriculum vitae				
b)	Does the laboratory ensure all personnel have the competence to perform laboratory activities for which they are responsible?				
c)	Does the laboratory have a process for managing competence of its personnel, including the frequency of competence assessment?				
d)	Is the information for demonstrating competence of its personnel documented?				
6.2.3	**Authorisation** Does the laboratory authorise personnel to perform laboratory activities pertaining to:				
a)	Selection, development, modification, validation, and verification of methods				
b)	Review, release and reporting of results				
c)	Use of laboratory information systems				
6.2.4	**Continuing education and professional development** Is there a continuing education programme available for all personnel who participate in managerial and technical processes? Are the suitability of programmes and activities periodically reviewed? <u>To consider:</u> • Management Review				
6.2.5	**Personnel records** Does the laboratory have procedures and retain records for				
a)	Determining the competence requirements				

Clause No	Description	Yes	No	N/A	Remarks
b)	Position descriptions				
c)	Training and re-training				
d)	Authorisation of personnel				
e)	Monitoring competence of personnel				
6.3	**Facilities and environmental conditions**				
6.3.1 6.3.2	Does the laboratory specify, monitor and record the requirements of facilities and environment conditions necessary for the performance of the laboratory activities? Facilities include pre-examination related facilities and other sites where examination procedures are performed, and POCT To produce • Procedures of the above • Monitoring records of the above				
6.3.2	**Facility controls** Are the facility controls implemented, recorded, monitored and periodically reviewed to include:				
a)	Control of access				
b)	Prevention of contamination, interference or adverse influence that arise from energy sources, lighting, ventilation, noise, water and waste disposal				
c)	Prevention of cross-contamination where examination procedures pose a risk or where work can be affected or influenced by the lack of separation				
d)	Provision of safety facilities and devices and regularly verifying their functioning				
e)	Maintenance of laboratory facilities in a functional and reliable condition				
6.3.3	**Storage facilities**				
a)	Does the laboratory have storage space to ensure the continuing integrity of samples, equipment, reagents, consumable, documents and records?				
b)	Are patient samples and materials used in the examination processes stored in a manner that prevents cross contamination and deterioration?				

Clause No	Description	Yes	No	N/A	Remarks
c)	Are storage and disposal facilities for hazardous materials and biological wastes appropriate to the classification of the materials in relation to the statutory or regulatory requirements?				
6.3.4	**Personnel facilities** Does the laboratory have adequate access to toilet facilities, supply of drinking water and storage of personal protective equipment and clothing?				
6.3.5	**Sample collection facilities** Does the sample collection facilities:				
a)	Enable collection to be undertaken in a manner does not invalidate results or adversely affect the quality of examinations?				
b)	Consider the privacy, comfort and needs of patients and accommodation of the accompanying persons during collection?				
c)	Provide separate patient reception and collection areas?				
d)	Maintain first aid materials for both patients and personnel?				
6.4	**<u>Equipment</u>** Does the laboratory have processes for selection, procurement, installation, acceptance testing, handling, transport, storage, use, maintenance and decommissioning of equipment to ensure proper functioning and prevent contamination or deterioration?				
6.4.2	**Equipment requirements**				
a)	Does the laboratory have access to equipment required for the correct performance of the laboratory activities?				
b)	Does the laboratory ensure compliance to ISO 15189: 2022 when using the equipment outside the laboratory's permanent control or the equipment manufacturer's functional specification?				
c)	Are equipment uniquely labelled, marked or otherwise identified and a register maintained?				
d)	Does the laboratory maintain and replace equipment as needed to ensure the quality of examination results?				

Clause No	Description	Yes	No	N/A	Remarks
6.4.3	**Equipment acceptance procedure** Does the laboratory verify that the equipment conforms to specified acceptability criteria before being placed or return into service? Does the laboratory ensure that measuring equipment are capable of achieving either the measurement accuracy and/or measurement uncertainty required to provide a valid result?				
6.4.4	**Instructions for use**				
a)	Does the laboratory have appropriate safeguards to prevent unintended adjustments of equipment that can invalidate examination results?				
b)	Are the equipment operated by trained, authorised and competent personnel?				
c)	Are instructions for used made readily available?				
d)	Is the equipment used as specified by the manufacturer; unless validated by the laboratory?				
6.4.5	**Equipment maintenance and repair**				
a)	Does the laboratory have a preventive maintenance programme based on manufacturer's schedule and instructions and deviations are recorded?				
b)	Is the equipment maintained in a safe working condition and working order?				
c)	Are defective equipment or outside specified requirements taken out of service clearly labelled or marked as being out of service until it has been verified to perform correctly? Does the laboratory examine the effect of the defect or deviation from specified requirements and initiate actions when non-conforming work occurs?				
d)	When applicable, does the laboratory decontaminate equipment before service, repair or decommissioning and provide suitable space for repairs and provide appropriate personal protective equipment?				
6.4.6	**Equipment adverse incident reporting** Are adverse incidents and accidents (attributed to specific equipment) investigated and reported to manufacturer and/or supplier and appropriate authorities, as required?				

Clause No	Description	Yes	No	N/A	Remarks
	Does the laboratory have procedures for responding to any manufacturer's recall or other notice and take actions recommended by the manufacturer?				
6.4.7	**Equipment records** Does the laboratory maintain records for each item of equipment which can influence the results of laboratory activities and is readily available for the lifespan of the equipment or longer? For example:				
a)	Manufacturer and supplier details or other unique identification, including software and firmware version				
b)	Dates of receipt, acceptance testing and entering into service				
c)	Evidence that equipment conforms with specified acceptability criteria				
d)	Current location				
e)	Condition when received				
f)	Manufacturer's instructions				
g) and h)	Preventive maintenance programme and activities performed by the laboratory or approved external service provider				
i)	Damage to, malfunction, modification or repair of the equipment				
j)	Equipment performance records – evidence of calibration / verifications, date, time and results				
h)	Status of equipment				
6.5	**Equipment calibration and metrological traceability**				
6.5.1	Does the laboratory specify calibration and traceability requirements sufficient to maintain consistent reporting of examination results? For quantitative methods of a measure analyte does the specification include calibration and metrological traceability requirements? For quantitative and qualitative methods that measure characteristics rather than discrete analytes, does the specification include reproducibility over time?				

Clause No	Description	Yes	No	N/A	Remarks
6.5.2	**Equipment calibration** Does the laboratory have procedures for the calibration of equipment that directly or indirectly affect examination results? Does the procedure include:				
a)	Conditions of use and manufacturer's instructions for calibration				
b)	Recording of the metrological traceability				
c)	Verification of the required measurement accuracy and the functioning of the measuring system at specified intervals				
d)	Recording the calibration status and the date of re-calibration				
e)	Ensure that correction factors when used are updated and recorded when re-calibration occurs				
f)	Handling of situations when calibration is out of control to minimise risk to service operation and to patients				
6.5.3	**Metrological traceability of measurement results**				
a)	Does the laboratory establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, with each contributing to the measurement uncertainty, linking them to an appropriate reference?				
b) and c)	Does the laboratory ensure that measurement results are traceable to the International System of Units (SI) where possible? <u>To consider</u> • Calibration provided by competent laboratory • Certified reference materials by competent producer • Direct realisation of SI units				
d)	For genetic examinations, is traceability to genetic reference sequence established?				
6.6	**<u>Reagents and consumables</u>**				
6.6.1	Does the laboratory have processes for the following for reagent and consumables? • Selection • Procurement • Reception • Storage				

Clause No	Description	Yes	No	N/A	Remarks
	• Acceptance testing • Inventory management				
6.6.2	**Reagent and consumables – Receipt and storage** Does the laboratory store reagents and consumables according to the manufacturers' specifications and monitor the environmental conditions where relevant? When the laboratory is not the receiving facility, do they verify the receiving facility has adequate storage and handling capabilities to maintain supplies in a manner that prevents damage and deterioration?				
6.6.3	**Reagent and consumables – Acceptance testing** Is new formulation of examination kits with changes in reagents or procedure, or new lot or shipment verified for performance before use? Are consumables that can affect the quality of examinations verified for performance before use?				
6.6.4	**Reagent and consumables – Inventory management** Does the laboratory establish an inventory management system for reagents and consumables and segregate reagents and consumables that have been accepted for use from those that have been neither inspected nor accepted for use?				
6.6.5	**Reagent and consumables – Instructions for use** Are instructions for use of reagents and consumables, including those provided by the manufacturers, readily available? Are reagent and consumables used according to the manufacturer's specifications?				
6.6.5	**Reagent and consumables – Adverse incident reporting** Are adverse incidents and accidents (attributed to specific reagents or consumables) investigated and reported to manufacturer and/or supplier and appropriate authorities, as required?				

Clause No	Description	Yes	No	N/A	Remarks
	Does the laboratory have procedures for responding to any manufacturer's recall or other notice and taking actions recommended by the manufacturer?				
6.6.7	**Reagents and consumables – Records** Does the laboratory record (but not limited to) the performance of each reagent and consumable contributing to the performance of examination?				
a)	Identity of the reagent or consumable				
b)	Manufacturer's name, and batch code/ lot number				
c)	Date of receipt and condition when received, expiry date, date of first use and where applicable date when taken out of service				
d)	Records that confirmed the reagent's or consumable's initial and ongoing acceptance for use When the laboratory uses reagents prepared, resuspended or combined in-house, the records shall include relevant information above and the following: • Reference to the person or persons undertaking the preparation • Dates of preparation and expiry				
6.7	**<u>Service agreement</u>**				
6.7.1	**Agreements with laboratory users** Does the laboratory have a procedure to establish and periodically review agreements for providing laboratory activities? Does the procedure include:				
a)	The requirements are adequately specified				
b)	The laboratory has the capability and resources to meet the requirements				
c)	Where applicable, the laboratory advises the user of the specific activities to be performed by referral laboratories and consultants Are laboratory users informed of changes to the agreement that can affect the examination results? Are records of reviews, including any significant changes retained?				
6.7.2	**Agreement with POCT operators**				

Clause No	Description	Yes	No	N/A	Remarks
	Does service agreements between the laboratory and other parts of the organisation using laboratory supported POCT ensure that respective responsibilities and authorities are specified and communicated?				
6.8	**Externally provided products and services**				
6.8.1	Does the laboratory ensure the suitability of externally provided products and services when such products and services are:				
a)	Intended for incorporation into the laboratory's own activities				
b)	Provided, in part or in full, directly to the user by the laboratory, as received from the external provider				
c)	Used to support the operation of the laboratory				
6.8.2	**Referral laboratories and consultants**				
	Does the laboratory communicate its requirements to referral laboratories and consultants who provide interpretation and advice for:				
a)	The procedures, examinations, reports and consulting activities to be provided				
b)	Management of critical results				
c)	Any required personnel qualifications and demonstration of competence				
	Does the referring laboratory have the responsibility for ensuring that examination results of the referral laboratory are provided to the person making the request?				
	Does the laboratory maintain a list of all referral laboratories and consultants?				
6.8.3	**Review and approval of externally provided products and services**				
	Does the laboratory have procedures and retain records for:				
a)	Defining, reviewing and approving the laboratory's requirements for all externally provided products and services				
b)	Defining the criteria for qualification, selection, evaluation of performance and re-evaluation of external providers				
c)	Referral of samples				

Clause No	Description	Yes	No	N/A	Remarks
d)	Ensuring that externally provided products and services conform to the laboratory's established requirements before they are used or directly provided to the user				
e)	Taking any actions arising from evaluation of the performance of external providers <u>To produce</u> • Procedures of the above • Records of the above				
7	**PROCESS REQUIREMENTS**				
7.1	Does the laboratory identify potential risks to patient care in the pre-examination, examination and post-examination processes? Are the identified risks and effectiveness of the mitigation processes monitored and evaluated according to the potential harm to the patient? Does the laboratory identify opportunities to improve patient care and develop a framework to manage these opportunities?				
7.2	**<u>Pre-examination processes</u>**				
7.2.1	Does the laboratory have procedures for all pre-examination activities and make them accessible to relevant personnel?				
7.2.2	**Laboratory information for patients and users** Does the laboratory have appropriate information available for its users and patients and sufficiently detailed to provide the laboratory users with a comprehensive understanding of the laboratory's scope of activities and requirements? Does the information include:				
a)	The location(s) of the laboratory, operating hours and contact information				
b)	The procedures for requesting and the collection of samples				
c)	The scope of laboratory activities and time for expected availability of results				
d)	The availability of advisory services				
e)	Requirements for patient consent				
f)	Factors known to significantly impact the performance of the examination or the interpretation of the results				

Clause No	Description	Yes	No	N/A	Remarks
g)	The laboratory's complaint process				
7.2.3	**Requests for providing laboratory examinations**				
7.2.3.1	<u>General</u>				
a)	Does the laboratory consider each request accepted by the laboratory as an agreement?				
b)	Does the examination request provide sufficient information to ensure: • Unequivocal traceability of the patient to the request and sample • Identification of requester and contact information • Identification of the examination(s) requested • Informed clinical and technical advice, and clinical interpretation				
c)	<u>To consider:</u> Is the examination request information provided in a format or medium as deemed appropriate by the laboratory and acceptable to the user?				
d)	Does the laboratory communicate with users or their representatives to clarify the user's request necessary for patient care?				
7.2.3.2	<u>Oral requests</u> Does the laboratory have procedure for managing oral requests for examinations? To consider • Record to document confirmation of the examination request to the laboratory within a given time				
7.2.4	**Primary sample collection and handling**				
7.2.4.1	<u>General</u> Does the laboratory have procedures for the collection and handling of primary samples? Is the information available to those responsible for sample collection? Does the laboratory periodically review the requirements for sample volume, collection device and preservatives for all sample types to ensure that neither insufficient nor excessive amounts of sample are collected, and samples are properly collected to preserve the analyte?				

Clause No	Description	Yes	No	N/A	Remarks
7.2.4.2	<u>Information for pre-collection activities</u> Does the laboratory provide sufficient information and instructions for pre-collection activities with to ensure that the integrity of sample is not compromised? Does this include the following:				
a)	Preparation of the patient				
b)	Type and amount of the primary sample to the collected with descriptions of the container and any necessary additives, and when relevant the order of collecting samples				
c)	Special timing of collection, where relevant				
d)	Provision of clinical information relevant to, or affecting sample collection, examination performance or result interpretation				
e)	Sample labelling for unequivocal identification of the patient, as well as source and site of sample and labelling, when several samples from same patient are to be collected, including multiple pieces of tissue or slides				
f)	The laboratory's criteria for acceptance and rejection of samples specific to the examinations requested				
7.2.4.3	<u>Patient consent</u>				
a)	Does the laboratory obtain the informed consent of the patient for all procedures carried out on the patient?				
b) and c)	*<u>To consider:</u>* *Are special procedures have a more detailed explanation and recorded consent, where applicable?* *If consent is not possible, does the laboratory carry out necessary procedure in the patient's best interest?*				
7.2.4.4	<u>Instructions for collection activities</u> Does the laboratory provide instructions for:				
a) and b)	Verification of the identity of the patient from whom a primary sample is collected and any pre—examination requirements (when relevant)				

Clause No	Description	Yes	No	N/A	Remarks
c)	Collection of primary samples, with description of the primary sample containers and any necessary additives, as well as the order of sample collection, where relevant				
d)	Labelling of primary samples in a manner that an unequivocal link with the patients from whom they are collected				
e)	Recording of the identity of the person collecting the primary sample and the collection date, and when relevant, recording of the collection time				
f)	Requirements for separating or dividing the primary sample when necessary				
g)	Stablisation and proper storage conditions before collected samples are delivered to the laboratory				
h)	Safe disposal of materials used in the collection process				
7.2.5	**Sample transportation**				
a)	Does the laboratory provide instructions for 1) Packing of samples for transportation 2) Ensuring the time between collection and receipt in the laboratory is appropriate for the requested examinations 3) Maintaining the temperature interval specified for sample collection and handling 4) Any specific requirements to ensure integrity of samples				
b)	If the integrity of a sample has been compromised and there is a health risk, is the organisation responsible for the transport of the sample notified immediately and action taken to reduce the risk and to prevent recurrence?				
c)	Does the laboratory establish and periodically evaluate adequacy of sample transportation systems?				
7.2.6	**Sample receipt**				
7.2.6.1	<u>Sample receipt procedure</u> Does the laboratory have a procedure for sample receipt which includes:				
a)	Unequivocal traceability of samples by request and labelling, to a uniquely identified patient and when applicable, the anatomical site				
b)	Criteria for acceptance and rejection of samples				

Clause No	Description	Yes	No	N/A	Remarks
c)	Date and time of receipt of the sample, when relevant				
d)	Identity of the person receiving the sample, when relevant				
e)	Evaluation of received samples, by authorised personnel, to ensure compliance with acceptability criteria relevant for the requested examination(s)				
f)	Instruction for samples specifically marked as urgent				
g)	Ensuring that all portions of the sample shall be unequivocally traceable to the original sample				
7.2.6.2	<u>Sample acceptance exceptions</u>				
a)	Does the laboratory have a process that considers the best interests of the patient in receiving care when a sample has been compromised?				
b)	Does the final report indicate the nature of the problem and where applicable advise caution when interpreting the results when a compromised clinically critical or irreplaceable sample is accepted?				
7.2.7	**Pre-examination handling, preparation and storage**				
7.2.7.1	<u>Sample protection</u> Does the laboratory have procedures and appropriate facilities for securing patient samples, ensuring sample integrity and preventing loss or damage during, handling, preparation and storage?				
7.2.7.2	<u>Criteria for additional examination requests</u> Does the laboratory procedures include time limits for requesting additional examinations on the same sample?				
7.2.7.3	<u>Sample stability</u> Taking into consideration the stability of the analyte in the primary sample, is the time between sample collection and performing the examination specified and monitored where relevant?				
7.3	**<u>Examination process</u>**				
7.3.1	**General**				

Clause No	Description	Yes	No	N/A	Remarks
a)	Does the laboratory select and use examination methods which have been validated for their intended use to assure the clinical accuracy of the examination for patient testing?				
b)	Does the performance specification for each examination method relate to the intended use of the examination and its impact on patient care?				
c)	Are all procedure and supporting instructions relevant to the laboratory activities kept up to date and readily available to personnel?				
d)	Does the personnel follow established procedures and identify of persons performing significant activities in examination processes recorded?				
e)	Are examination methods periodically evaluated by authorised personnel to ensure they are clinically appropriate for the requests received?				
7.3.2	**Verification of examination methods**				
a)	Does the laboratory have a procedure to verify that it can properly perform examination methods before introducing into use (i.e. by ensuring that the required performance as specified by the manufacturer or method can be achieved)?				
b)	Are the performance specifications for the examination method confirmed during the verification process relevant to the intended use of the examination results?				
c)	Does the laboratory ensure the extent of the verification is sufficient to ensure the validity of the results pertinent to clinical decision making?				
d)	Are the verification results and records reviewed by personnel with appropriate authorisation and competence to meet the specific requirements?				
e)	If the method is revised by the issuing body, does the laboratory repeat verification to the extent necessary?				
f)	Are the following records of verification retained? 1) Performance specification to be achieved 2) Results obtained 3) A statement of whether the performance specifications were achieved and if not, action taken				
7.3.3	**Validation of examination methods**				
a)	Does the laboratory validate examination methods derived from the following sources? 1) Laboratory designed or developed methods				

Clause No	Description	Yes	No	N/A	Remarks
	2) Methods used outside their originally intended scope 3) Validated methods subsequently modified				
b)	Is the validation as extensive as is necessary and confirm through the provision of objective evidence in the form of performance specifications, that the specific requirements for the intended use of the examinations have been fulfilled? Does the laboratory ensure that the extent of validation of an examination method is sufficient to ensure the validity of results pertinent to clinical decision making?				
c)	Are the validation results and records reviewed by personnel with appropriate authorisation and competence to meet the specific requirements?				
d)	When changes are proposed to a validated examination method, is the clinical impact reviewed and a decision made as to whether to implement the modified method?				
e)	Are the following records of validation retained? 1) Validation procedure used 2) Specific requirements for the intended use 3) Determination of the performance specification of the method 4) Results obtained 5) Statement on the validity of the method, detailing its fitness for the intended use				
7.3.4	**Evaluation of measurement uncertainty (MU)**				
a)	Is the MU of the measured quantity values evaluated and maintained for its intended use? Is the MU compared against performance specifications and documented?				
b)	Are MU evaluations regularly reviewed?				
c)	If U is not possible or relevant, is the rationale for exclusion from MU estimation documented?				
d)	Is the MU information made available to laboratory users on request?				
e)	When users have inquiries on MU, does the laboratory's response take into account other sources of uncertainty?				

Clause No	Description	Yes	No	N/A	Remarks
f)	If the qualitative result of an examination relies on a test which produces quantitative output data and is specified as positive or negative (based on a threshold), is the MU in the output quantity estimated using representative positive and negative samples? • MU in intermediate measure steps or IQC results which produce quantitative data should also be considered for key parts of the process				
g)	<u>*To consider:*</u> *For examinations with qualitative results, is the MU in intermediate measurement steps or IQC results considered?*				
h)	<u>*To consider:*</u> *Is MU also taken into consideration when performing verification or validation of a method?*				
7.3.5	**Biological reference intervals and clinical decision limits**				
a)	Are biological reference intervals and clinical decision limits defined and their basis recorded to reflect the patient population served by the laboratory? *Note: Biological reference values provided by the manufacturer can be used by the laboratory if the population base of these values is verified and deemed acceptable by the laboratory.*				
b)	Are biological reference intervals and clinical decision limits periodically reviewed and changes communicated to users?				
c)	Does the laboratory review the impact on associated biological reference intervals and clinical decision limits when changes are made to an examination or pre-examination method and communicated to the users when applicable?				
d)	<u>*To consider:*</u> *For examinations that identify presence or absence, is the biological reference interval the characteristic to be identified?*				
7.3.6	**Documentation of examination procedure**				
a)	Does the laboratory document its examination procedures to the extent necessary to ensure the consistent application of its activities and the validity of its results?				

Clause No	Description	Yes	No	N/A	Remarks
b)	Are procedures written in a language understood by laboratory personnel and be available in appropriate locations?				
c)	Are abbreviated document content corresponded to the procedure?				
e)	Does the laboratory explain to users the implication when they make a validated change to an examination procedure which could affect the interpretation of results?				
f)	Are all documents associated with the examination subjected to documented control?				
7.3.7	**Ensuring the validity of examination results**				
7.3.7.1	Does the laboratory have a procedure for monitoring the validity of results and the monitoring planned and reviewed? Are the resulting data recorded in a way that trends and shifts are detectable and where practicable, statistical techniques applied to review the results?				
7.3.7.2	<u>Internal quality control (IQC)</u>				
a)	Does the laboratory have an IQC procedure for monitoring the ongoing validity of examination results?				
b)	Does the laboratory select IQC material that is fit for its intended purpose? When selecting IQC material, are the following factors considered? 1) Stability with regard to the properties of interest 2) The matrix is as close as possible to that of patient samples 3) Reacts to the examination method in a manner as close as possible to patient samples 4) Provides a clinical relevant challenge to the examination method, has concentration levels at or near clinical decision limits and when possible, covers the measurement range of the examination method				
c)	If the appropriate IQC material is not available, does the laboratory consider the use of other methods for IQC?				
d)	Is the IQC performed at a frequency that is based on the stability and robustness of the examination method and the risk of harm to the patient from an erroneous result?				

Clause No	Description	Yes	No	N/A	Remarks
e)	Is the resulting data recorded that trends and shifts are detectable, and where applicable, statistical methods applied to review the results?				
f)	Is the IQC data reviewed with defined acceptability criteria at regular intervals and in a timeframe that allows a meaningful indication of current performance?				
g)	Does the laboratory prevent the release of patient results in the event that IQC fails the acceptability criteria? 1) When IQC defined acceptability criteria are not fulfilled and indicate results are likely to contain clinically significant errors, is the results rejected and relevant patient samples re-examined after the error has been corrected? 2) Are the results from patient samples that were examined after the last successful IQC event evaluated?				
7.3.7.3	<u>External quality assessment (EQA)</u>				
a)	Does the laboratory monitor its performance of examination methods by compariing with results of other laboratories?				
b)	Does the laboratory establish a procedure for EQA enrolment, participation and performance for examination methods used, where such programmes are available?				
c)	Are EQA samples processed by personnel who routinely perform pre-examination, examination and post-examination procedures?				
d)	Does the EQA programme selected by the laboratory 1) Have the effect of checking pre-examination, examination and post-examination processes 2) Provide samples that mimic patient samples for clinically relevant challenges 3) Fulfil ISO/IEC 17043 requirements				
f)	Does the laboratory use alternative methodologies to monitor examination method performance when an EQA programme is not available or not considered suitable? Does the laboratory justify the rational of the chosen alternative and provide evidence of its effectiveness?				
g)	Is the EQA data reviewed at regular interval with specified acceptability criteria, in a time frame which allow for a meaningful indication of current performance?				

Clause No	Description	Yes	No	N/A	Remarks
h)	Are appropriate actions taken when EQA results fall outside specified acceptability criteria?				
i)	Where the impact is determined to be clinically significant, is a review performed for patient results that could have been affected, with the need for amendment considered and users advised as appropriate?				
7.3.7.4	Comparability of examination results				
a)	Does the laboratory establish a procedure to ensure the comparability of results for patient samples throughout the clinically significant intervals? • Different methods or equipment (or both) • Same examination performed at different sites				
b)	Does the laboratory record the results of comparability performed and its acceptability?				
c)	Does the laboratory periodically review the comparability of results?				
d)	Are the impact of differences identified on biological reference intervals and clinical decision limits evaluated and acted upon?				
e)	Does the laboratory inform users of any clinically significant differences in comparability of results?				
7.4	**Post-examination processes**				
7.4.1	**Reporting of results**				
7.4.1.1	General				
a)	Are examination results reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedure? Does the report include all available information necessary for the interpretation of the results?				
b)	Does the laboratory have a procedure to notify users when examination results are delayed, based on the impact of the delay on the patient?				
c)	Are all information associated with issued reports retained in accordance with management system requirements?				
7.4.1.2	Result review and release				
	Are results reviewed and authorised prior to release?				

Clause No	Description	Yes	No	N/A	Remarks
	Does the laboratory ensure that authorised personnel review the results of examinations and evaluate them against IQC and, as appropriate, available clinical information and previous examination results? Are responsibilities and procedure for how examination results are released for reporting specified?				
7.4.1.3	Critical result reports When examination results fall within established critical decision limits:				
a)	Is the user or other authorised person notified as soon as relevant?				
b)	Actions taken are documented (including date, time, responsible person, person notified, results conveyed, verification of accuracy of communication, any difficulties encountered in notification)?				
c)	Does the laboratory have an escalation procedure for laboratory when a responsible person cannot be contacted?				
7.4.1.4	Special considerations for results				
a)	When agreed with the user, is the results reported in a simplified way?				
b)	When the results are transmitted as a preliminary report, is the final report forwarded to the user?				
c)	For results that are provided orally, are records including details of verification of accuracy of communication kept and follow-up by a report?				
d)	*To consider:* *Does the laboratory provide special counselling for examination results with serious implications and does the laboratory management ensure that these results are not communicated to the patient without the opportunity for adequate counselling?*				
e)	*To consider:* *Have results of laboratory examinations that have been anonymised (used for such purposes as epidemiology, demography, or other statistical analyses, provided that all risks to patient privacy and confidentiality) mitigated and in accordance with any either legal or regulatory requirements, or both?*				

Clause No	Description	Yes	No	N/A	Remarks
7.4.1.5	Automated selection, review, release and reporting of results When the laboratory implements a system for automated selection, review, release and report of results, are procedures established for:				
a)	The criteria for automated selection, review and release are specified, approved, readily available and understood by personnel responsible for authorising the release of results?				
b)	Is the criteria validated and approved before use, regularly reviewed and verified after changes to the reporting system that can affect their proper functioning?				
c)	Is the results selected by an automated reporting system for manual review identifiable? • Date and time of selection and review • Identity of the reviewer				
d)	When necessary, rapid suspension of automated selection, review, release and reporting is applied.				
7.4.1.6	Requirements for reports Does each report include the following report (unless the laboratory has documented reasons for omitting any items)?				
a)	On each page of the report, the unique patient identification, date of primary sample collection and the date of issue of the report				
b)	Identification of the laboratory issuing the report				
c)	Name or other unique identifier of the user				
d)	Type of primary sample and any specific information necessary to describe the sample				
e)	Clear, unambiguous identification of the examinations performed				
f)	Identification of the examination method used, where relevant, including, where possible and necessary, harmonised (electronic) identification of the measurand and measurement principle				
g)	Examination results with, where appropriate, the units of measurement (reported in SI units, units traceable to SI units, or any other applicable units)				
h)	Biological reference intervals, clinical decision limits, likelihood ratios, or diagrams supporting clinical decision limits as necessary				

Clause No	Description	Yes	No	N/A	Remarks
i)	Identification of examinations undertaken as part of a research and development programme and for which no specific claims on measurement performance are available.				
j)	Identification of the person(s) reviewing the results and authorising the release of the report (if not contained in the report, readily available when needed)				
k)	Identification of any results that need to be considered as preliminary				
l)	Indication of any critical results				
m)	Unique identification that all its components are recognised as a portion of a complete report and a clear identification of the end				
7.4.1.7	<u>Additional information for reports</u>				
a)	When necessary for patient care, is the time of primary sample collection included?				
b)	Is the time of report release (if not contained in the report) readily available?				
c)	Does the laboratory identify examinations or parts of examinations performed by a referral laboratory, including information provided by consultants, without alteration and the name of the laboratory performing the examinations?				
d)	When applicable, does the report include interpretation of results and comments on 1) Sample quality and suitability that can compromise the clinical value of examination results 2) Discrepancies when examinations are performed by different procedures or in different locations 3) Possible risk of misinterpretation when different units of measurement are in use 4) Result trends or significant changes over time				
7.4.1.8	<u>Amendments to reported results</u> Does the laboratory ensure that procedures for the issue of amended or revised reports include the following:				
a)	The reason for the change and included in the revised report				
b)	Revised results delivered in the form of an additional document or data transfer, and clearly identified as having been revised, with the date and patient's identity in the original report indicated				

Clause No	Description	Yes	No	N/A	Remarks
c)	The user is made aware of the revision				
d)	When a new report is issued, it is uniquely identified and contain a reference and traceability to the original report it replaces.				
e)	Retention of records of the revisions				
7.4.2	**Post-examination handling of samples** Does the laboratory specify the length of time samples are to be retained following examination and the conditions under which samples are to be stored? Does the laboratory ensure that after the examination,				
a)	Patient and source identification of the sample are maintained?				
b)	Suitability of the sample of additional examination is known?				
c)	Sample is stored in a manner that optimally preserves suitability for additional examination?				
d)	Sample can be located and retrieved?				
e)	Sample is discarded properly?				
7.5	**<u>Nonconforming work</u>** Does the laboratory have a process to address any aspect of its laboratory activities or examinations that do not conform to its own procedures' quality specifications, or the user requirements? Does the process ensure that:				
a)	The responsibilities and authorities for the management of nonconforming work are specified?				
b)	Intermediate and long-term actions are specified and based upon the risk analysis process established by the laboratory?				
c)	Examinations are halted, and reports withheld when there is a risk of harm to patients?				
d)	An evaluation is made of the clinical significance of the nonconforming work, including an impact analysis on examination results which were or could have been released prior to identification of the nonconformance?				

Clause No	Description	Yes	No	N/A	Remarks
e)	A decision is made on the acceptability of the nonconforming work?				
f)	When necessary, examination results are revised and the user is notified?				
g)	The responsibility for authorising the resumption of work is specified?				
	Does the laboratory implement corrective action commensurate with the risk of recurrence of the nonconforming work?				
	Does the laboratory retain records of nonconforming work and actions as specified in a) to g)?				
7.6	**Control of data and information management**				
7.6.1	Does the laboratory have access to the data and information needed to perform laboratory activities?				
7.6.2	**Authorities and responsibilities for information management**				
	Does the laboratory ensure that the authorities and responsibilities for the management of the information system are specified, including the maintenance and modification to the information systems that can affect patient care?				
	Is the laboratory ultimately responsible for the laboratory information systems?				
7.6.3	**Information systems management**				
	Has the system(s) used for the collection, processing, recording reporting, storage or retrieval of examination data and information:				
a)	Validated by the supplier and verified for functionality by the laboratory before introduction? Are changes to the system (including laboratory software configuration or modification to commercial off-the-shelf software) authorised, documented and validated before implementation?				
b)	Documented, and the documentation readily available to authorised users, including that for day to day functioning of the system?				
c)	Implemented (taking cybersecurity into account) to protect the system from unauthorised access and safeguard data against tampering of loss?				

Clause No	Description	Yes	No	N/A	Remarks
d)	Operated in an environment that complies with supplier specifications or provides conditions which safeguard the accuracy of manual recording and transcription?				
e)	Maintained in a manner that ensures the integrity of data and information and includes the recording of system failures and the appropriate immediate and corrective actions? Are calculations and data transfers checked in an appropriate and systematic manner?				
7.6.4	**Downtime plans** Does the laboratory have planned processes to maintain operations in the event of failure or during downtime in information systems that affects the laboratory's activities? • Includes automated selection and reporting of results				
7.6.5	**Off site management** When the laboratory information system(s) are managed and maintained off-site or through an external provider, does the laboratory ensure that the provider or operator of the system complies with all applicable requirements in ISO 15189: 2022?				
7.7	**Complaints**				
7.7.1	**Process** Does the laboratory have a process for handling complaints that include:				
a)	A description of the process for receiving, substantiating and investigating the complaint, and deciding what actions shall be taken in response?				
b)	Tracking and recording the complaint, including the actions undertaken to resolve it?				
c)	Ensuring appropriate action is taken? Is the description of the process for handling complaints publicly available?				
7.7.2	**Receipt of complaint**				
a)	Upon receipt of a complaint, does the laboratory confirm whether the complaint relates to laboratory activities that the laboratory is responsible for and, if so, resolve the complaint?				

Clause No	Description	Yes	No	N/A	Remarks
b)	Is the laboratory receiving the complaint responsible for gathering all necessary information to determine whether the complaint is substantiated?				
c)	Does the laboratory acknowledge receipt of the complaint and provide the complainant with the outcome and, if applicable the progress report?				
7.7.3	**Resolution of complaint** Does the laboratory ensure that impartiality is maintained by appointing persons who are not involved in the subject of the complaint in question to decide, review, approve the resolution of complaints.				
7.8	**<u>Continuity and emergency preparedness planning</u>** Does the laboratory ensure that risks associated with emergency situations or other conditions when laboratory activities are limited, or unavailable, are identified? Does the laboratory have a coordinated strategy that involves plans, procedures and technical measures to enable continued operations after a disruption? Are the plans periodically tested and the planned response capability exercised, where practicable? Does the laboratory				
a)	Establish a planned response to emergency situations, taking into account the needs and capabilities of all relevant laboratory personnel?				
b)	Provide information and training as appropriate to relevant laboratory personnel?				
c)	Respond to actual emergency situations?				
d)	Take action to prevent or mitigate the consequences of emergency stations, appropriate to the magnitude of the emergency and the potential impact?				
8	**MANAGEMENT SYSTEM REQUIREMENTS**				
8.1	**<u>General Requirements</u>**				
8.1.1	**General** Does the laboratory establish, document, implement and maintain a management system to support and demonstrate the consistent fulfilment of the requirements of ISO 15189: 2022?				

Clause No	Description	Yes	No	N/A	Remarks
	Does management system include at minimally the following • Responsibilities • Objectives and policies • Documented information • Actions to address risks and opportunities for improvement • Continual improvement • Corrective actions • Evaluations and internal audits • Management reviews				
8.1.2	Does the quality management system support and demonstrate the consistent fulfilment of the requirements of Clause 4 to 7 and 8.2 to 8.9? *E.g. the laboratory may implement a quality management system in accordance with the requirements of ISO 9001.*				
8.1.3	Does the laboratory ensure that persons doing work under the laboratory's control are aware of the following?				
a)	Relevant objectives and policies?				
b)	Their contribution to the effectiveness of the management system?				
c)	The consequences of not conforming with the management system requirements?				
8.2	**Management system documentation**				
8.2.1	Does the laboratory establish, document and maintain objectives and policies for the fulfilment of the purpose of ISO 15189: 2022 and ensure that the objectives and policies are acknowledged and implemented at all levels of the laboratory organisation?				
8.2.2	Does the objectives and policies address the competence, quality and consistent operation of the laboratory?				
8.2.3	Does the laboratory management provide evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness?				
8.2.4	Are all documentation, processes, systems and records related to the fulfilment of the requirements of ISO 15189: 2022 included, referenced or linked to the management system?				

Clause No	Description	Yes	No	N/A	Remarks
8.2.5	Does all personnel involved in laboratory activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities?				
8.3	**Control of management system documentation**				
8.3.1	Does the laboratory control the documents (internal and external) that related to the fulfilment of ISO 15189: 2022?				
8.3.2	**Control of documents**				
	Does the laboratory ensure that				
a)	Documents are uniquely identified?				
b)	Documents are approved for adequacy before issue by authorised personnel who have the expertise and competence to determine adequacy?				
c)	Documents are periodically reviewed and updated as necessary?				
d)	Relevant versions of applicable documents are available at points of use and distribution is controlled?				
e)	Changed and the current revision status are identified?				
f)	Documents are protected from unauthorised changes, deletion and removal?				
g)	Documents are protected from unauthorised use?				
h)	The unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose?				
i)	At least one paper / electronic copy of each obsolete controlled document is retained for a specific time period or in accordance with applicable specified requirements?				
8.4	**Control of records**				
8.4.1	**Creation of records**				
	Does the laboratory establish and retain legible records to demonstrate fulfilment of ISO 15189: 2022?				
	Are records related at the time of each activity that affects the quality of an examination performed?				

Clause No	Description	Yes	No	N/A	Remarks
8.4.2	**Amendment of records** Does the laboratory ensure that amendments to records can be traced to previous version or original observations? Are the original and amended data and files kept, including the date and where relevant time of alteration, indication of the altered aspects and the personnel making the alterations?				
8.4.3	**Retention of records**				
a)	Does the laboratory implement the procedures for the: • identification, • storage, • protection from unauthorised access and changes, • back-up, • archive, • retrieval, • retention time • disposal of records				
b)	Are retention times for records specified?				
c)	Are the reported examination results retrievable for as long as necessary or as required?				
d)	Are all records accessible throughout the entire retention period? Are the records legible (in whatever medium) and available for laboratory management review?				
8.5	**Actions to address risks and opportunities for improvement**				
8.5.1	Does the laboratory identify risks and opportunities for improvement associated with the laboratory activities to:				
a)	Prevent or reduced undesired impacts and potential failures in the laboratory activities?				
b)	Achieve improvement, by acting on opportunities?				
c)	Assure that the management system achieves it intended results?				
d)	Mitigate risks to patient care?				
e)	Help achieve the purpose and objectives of the laboratory?				
8.5.2	**Acting on risks and opportunities for improvement**				

Clause No	Description	Yes	No	N/A	Remarks
	Does the laboratory prioritise and active on identified risks? Are actions taken to address risks proportional to the potential impact on laboratory examination results, patient and personnel safety? Does the laboratory record decisions made and actions taken on risks and opportunities? Does the laboratory integrate and implement actions on identified risks and improvement opportunities into its management system and evaluate the effectiveness?				
8.6	**<u>Improvement</u>**				
8.6.1	**Continual improvement**				
a)	Does the laboratory continually improve the effectiveness of the management system, including the pre-examination, examination and post-examination processes as stated in the objectives and policies?				
b)	Does the laboratory identify and select opportunities for improvement and develop, document and implement any necessary actions? Are the improvement activities directed at areas of highest priority based on risk assessments and the opportunities identified?				
c)	Are the effectiveness of the actions taken evaluated?				
d)	Does the laboratory management ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care?				
e)	Does the laboratory management communicate to personnel its improvement plans and related goals?				
8.6.2	**Laboratory patients, user, and personnel feedback** Does the laboratory seek and analyse feedback from its patients, users and personnel? <u>To Produce</u> Records of feedback Is communication provided to personnel on actions taken arising from their feedback?				
8.7	**<u>Nonconformities and corrective actions</u>**				

Clause No	Description	Yes	No	N/A	Remarks
8.7.1	**Actions when nonconformity occurs** When a nonconformity occur, does the laboratory				
a)	Respond to the non-conformity and 1) take immediate action to control and correct the nonconformity? 2) address the consequences, with a particular focus on patient safety, including escalation to the appropriate person?				
b)	Determine the cause(s) of nonconformity				
c)	Evaluate the need for corrective action to eliminate the cause(s) of the nonconformity, in order to reduce the likelihood of recurrence or occurrence elsewhere by: 1) reviewing and analysing the nonconformity 2) determining whether similar nonconformities exist, or potentially occur 3) assessing the potential risk(s) and effect(s) if the nonconformity recurs				
d)	Implement any action needed				
e)	Review and evaluate the effectiveness of any corrective action taken				
f)	Update risks and opportunities for improvement, as needed				
g)	Make changes to the management system, if necessary				
8.7.2	Are the corrective actions appropriate to the effects of the nonconformities encountered and mitigate the identified cause(s)?				
8.7.3	Does the laboratory retain records of the				
a)	Nature of nonconformities, cause(s) and any subsequent action taken?				
b)	Evaluation of the effectiveness of any corrective action?				
8.8	**Evaluations**				
8.8.1	Does the laboratory conduct evaluations at planned intervals to demonstrate that the management, support, and pre-examination, examination and post-examination processes meet the needs and requirements of patients and laboratory users?				
8.8.2	**Quality indicators**				

Clause No	Description	Yes	No	N/A	Remarks
	Does the laboratory plan the process of monitoring quality indicators and ensure that indicators periodically reviewed to ensure continued appropriateness? This includes establishing objectives, methodology, interpretation, limits, action plan and duration of monitoring.				
8.8.3	**Internal audits**				
8.8.3.1	Does the laboratory conduct internal audits at planned intervals? Does the management system				
a)	Conform to the laboratory's own requirements for its management system, including the laboratory activities?				
b)	Conforms to ISO 15189: 2022?				
c)	Effectively implemented and maintained?				
8.8.3.2	Does the laboratory plan, establish, implement and maintain an internal audit programme? Does the programme include:				
a)	Priority given to risk to patients from laboratory activities?				
b)	A schedule which takes into consideration • Priority given to risk to patients from laboratory activities • The outcomes of both external evaluations and previous internal audits • The occurrence of nonconformities, incidents and complaints • Changes affecting the laboratory activities				
c)	Specified audit objectives, criteria and scope for each audit				
d)	Selection of auditors who are trained, qualified and authorised to assess the performance of the laboratory's management system, and whenever resource permits, independent of the activity to be audited?				
e)	Ensure objectivity and impartiality of the audit process?				
f)	Ensuring that the results of the audits are reported to the relevant personnel				
g)	Implementation of appropriate correction and corrective actions without undue delay				

Clause No	Description	Yes	No	N/A	Remarks
h)	Retention of records as evidence of the implementation of the audit programme and audit results				
8.9	**Management reviews**				
8.9.1	Does the laboratory management review its management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness?				
8.9.2	**Review input** Does the inputs recorded and include:				
a)	• Status of actions from previous management review • Internal and external changes to the management system • Changes in the volume and type of laboratory activities • Adequacy of resources				
b)	Fulfilment of objectives and suitability of policies and procedures				
c)	• Outcomes of recent evaluations • Process monitoring using quality indicators • Internal audits • Analysis of non-conformities • Corrective actions • Assessment by external bodies				
d)	Patients, user and personnel feedback and complaints				
e)	Quality assurance of result validity				
f)	Effectiveness of any implemented improvements and actions taken to address risks and opportunities for improvement				
g)	Performance of external providers				
h)	Results of participation in interlaboratory comparison programmes				
i)	Evaluation of POCT activities				
j)	Other relevant factors (e.g. monitoring activities and training)				
8.9.3	**Review output** Does the laboratory record the output with decision and actions related to:				

Clause No	Description	Yes	No	N/A	Remarks
a) b) c) d) e)	The effectiveness of the management system and its process? Improvement of the laboratory activities related to the fulfilment of the requirements of ISO 15189: 2022 Provision of required resources Improvement of services to patients and users Any need for change Does the laboratory management ensure that actions arising from management review are completed within a specific time frame? Are the conclusions and actions arising from management reviews communicated to laboratory personnel?				
8	**ADDITIONAL REQUIREMENTS FOR POCT**				
	Does the governing body of the organisation ultimately responsible for ensuring that appropriate processes are in place to monitor the accuracy and quality of POCT conducted within the organisation? Are the service agreements between the laboratory and locations using laboratory supported POCT ensure that respective responsibilities and authorities are specified and communicated within the organisation and are have been approved clinically? Is there an appointed person with appropriate training and experience to be responsible for POCT quality? This appointed person shall have the following: • Appropriate training and experience to manage training and competency assessment of personnel performing POCT • Develop, implement and maintain an appropriate theoretical and practical training programme for POCT personnel				
SAC-SINGLAS Requirements					
A. 1.	**<u>Key Personnel</u>** Do the key personnel still occupy appropriate positions in the staff structure to be responsible for the adequacy of test results?				

Clause No	Description	Yes	No	N/A	Remarks
2.	Do the key personnel still retain sufficient contact time with testing procedures to maintain the ability for critical evaluation of results?				
B.	**SAC-SINGLAS Accredited Reports and Use of Mark**				
1.	Does the laboratory / facility comply with the terms and conditions for SAC-SINGLAS accredited report as stipulated in SAC 02?				
C.	**Follow up on last year findings**				
D.	**Other Observation and Comments** Safety				
F.	**Additional Notes**				